

REMARKS

Claims 1-6, 9, 11 and 32-36 are pending in the Application and are now presented for examination. Claims 1, 3, 11 and 35 have been amended. Claim 10 has been cancelled, without prejudice and without disclaimer of subject matter. No new matter has been added. Claims 1 and 11 are independent.

On page 2 of the Office Action, acknowledgement is made that the prior amendments overcame the 35 U.S.C. §112 rejections.

On page 2 of the Office Action, Claim 10 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claim 10 has been cancelled, rendering its rejection moot. Applicant notes that the cancellation of Claim 10 is not an acquiescence or acknowledgement of the propriety of the rejection, but rather is made in an effort to advance prosecution of the remaining claims.

On page 3 of the Office Action, Claims 1-3, 9, 11, and 32-35 are rejected under 35 U.S.C. §102(b) as being anticipated by Joye et al. (6,428,534). In order to anticipate a claim, a reference must disclose each and every element of the claim.

Amended independent Claims 1 recites, in part, “determining a target pressure for inflation of the expandable membrane,” and “controllably inflating the expandable membrane to at least the predetermined target pressure.” Independent Claim 11 recites, in part, “controllably inflating the expandable membrane...to a preselected target pressure level in order to provide sufficient mechanical force against the desired tissue region.” Joye ‘534 makes no such disclosure. At Col. 8, lines 5-20, Joye discloses “the use of a feedback control system for

initiating, regulating, and halting the supply of cryogenic fluid from fluid supply system 14.”

But Joye’s general disclosure of a “control system” is not sufficient to anticipate the above-claimed features. Claims 1 and 11 are allowable for at least this reason.

Claims 1 and 11 further recite, in part, “ablating a desired tissue region, wherein the pressure in the expandable membrane during ablation exceeds the target pressure.” Page 3 of the Office Action states, “the pressure during the cryogen cycle...would be greater than the pressure in the balloon during the flushing cycle.” However, supporting rationale for this conclusory statement is lacking. Joye makes no such disclosure, and indeed, is not cited as supporting this premise. To the extent the Office Action suggests the pressure differential is inherent, Applicant notes that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic (MPEP §2112).

For the reasons stated above, the cited art does not support the rejection under 35 U.S.C. §102 of independent Claims 1 and 11, or their dependent claims. Accordingly, Applicant respectfully requests a withdrawal of the rejection.

On page 3 of the Office Action, Claims 4, 5, and 6 are rejected under 35 U.S.C. §103(a) as being unpatentable over Joye et al. (‘534) in view of the teaching of Edwards (6,258,087). Claims 4, 5, and 6 recite additional limitations which, in conformity with the features of their corresponding independent claim, are not disclosed or suggested by the art of record. The dependent claims are therefore believed patentable. However, the individual reconsideration of the patentability of each claim on its own merits is respectfully requested.

On page 4 of the Office Action, Claim 10 is rejected under 35 U.S.C. §103(a) as being unpatentable over Joye et al. ('534) in view of the teaching of Stern (5,443,470). Claim 10 has been cancelled, rendering its rejection moot.

On page 4 of the Office Action, Claims 3, 35 and 36 are rejected under 35 U.S.C. §103(a) as being unpatentable over Joye et al. ('534) in view of the teaching of Joye et al. (2002/0045894). Claims 3, 35 and 36 recite additional limitations which, in conformity with the features of their corresponding independent claim, are not disclosed or suggested by the art of record. The dependent claims are therefore believed patentable. However, the individual reconsideration of the patentability of each claim on its own merits is respectfully requested.

On page 5 of the Office Action, Claims 1-3, 9, 11, and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Droegemueller (3,924,628) in view of the teaching of Joye et al. ('534). Independent Claims 1 and 11 state controllably inflating the expandable membrane to at least "the predetermined target pressure" or "a preselected *target pressure*," and "ablating a desired tissue region, wherein the pressure in the expandable membrane during ablation *exceeds the target pressure*." Droegemueller discloses a bladder contacting the uterus, where the pressure of the bladder "should preferably be *maintained* at or about 2 or 3 p.s.i. to avoid any possible risk of injury to the patient,"(Col. 3:58-62)(emphasis added). This sole reference to bladder pressure explicitly recites *maintaining* a pressure, and makes no mention of *exceeding* that pressure whatsoever. Maintaining a single bladder pressure during operation is not "ablating a desired tissue region, wherein the pressure in the expandable membrane during ablation *exceeds the target pressure*," as stated in Applicants' Claims 1 and 11. Indeed, the Office

Action fails to even address this claimed feature. The citation to the Joye '534 reference fails to cure Droegmueller's lack of disclosure.

Accordingly, Droegemueller and Joye, whether considered alone or in combination, fail to disclose every feature of the claimed invention, as required for a *prima facie* case of obviousness. The rejection of Claims 1 and 11 is thus unsupported, and a withdrawal of the rejection is respectfully requested. Dependent Claims 2-3, 9 and 32-35 are also believed allowable as they depend from independent Claims 1 and 11.

On page 6 of the Office Action, Claims 4, 5, and 6 are rejected under 35 U.S.C. §103(a) as being unpatentable over Droegemueller ('628) and Joye et al. ('534) and further in view of the teaching of Edwards (6,258,087). Claims 4, 5, and 6 recite additional limitations which, in conformity with the features of their corresponding independent claim, are not disclosed or suggested by the art of record. The dependent claims are therefore believed patentable.

On page 7 of the Office Action, Claim 10 is rejected under 35 U.S.C. §103(a) as being unpatentable over Droegemueller ('628) and Joye et al. ('534) in view of the teaching of Stern ('470). Claim 10 has been cancelled, rendering its rejection moot.

On page 7 of the Office Action, Claims 3, 35, and 36 are rejected under 35 U.S.C. §103(a) as being unpatentable over Droegemueller ('628) and Joye et al. ('534) and further in view of the teaching of Joye et al. ('894). Claims 3, 35, and 36 recite additional limitations which, in conformity with the features of their corresponding independent claim, are not disclosed or suggested by the art of record. The dependent claims are therefore believed patentable.

For all of the above reasons, the claim objections are believed to have been overcome placing Claims 1-6, 9, 11 and 32-36 in condition for allowance, and reconsideration and allowance thereof is respectfully requested.

The Examiner is encouraged to telephone the undersigned to discuss any matter that would expedite allowance of the present application.

The Commissioner is hereby authorized to credit overpayments or charge payment of any additional fees associated with this communication to Deposit Account No. 502104.

Respectfully submitted,

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